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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional)	
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	T	9099-4	1
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail	Application Number		Filed
in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]	10/005,889		11/7/01
on	First Named Inventor		
Signature	Robert Black		
	Art Unit	E	xaminer
Typed or printed name Audra Wooten	1641		Gary W. Counts
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.			
This request is being filed with a notice of appeal.			
The review is requested for the reason(s) stated on the attached sheet(s).  Note: No more than five (5) pages may be provided.			
I am the			
applicant/inventor.  Signature			
assignee of record of the entire interest.  See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.  (Form PTO/SB/96)	Robert N. Crouse Typed or printed name		
attorney or agent of record.  Registration number 44,635	(919) 854-1400 Telephone number		
		reiepr	ione number
attorney or agent acting under 37 CFR 1.34.	June 30, 2006		
Registration number if acting under 37 CFR 1.34	Date		
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.  Submit multiple forms if more than one signature is required, see below*.			
Table of forms are submitted	· · ·		

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



# RESPONSE UNDER 37 C.F.R. § 1.116 EXPEDITED PROCEDURE – EXAMINING GROUP 1641

Attorney Docket No.: 9099-4

**PATENT** 

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Robert D. Black Group: 1641

Serial No.: 10/005,889 Examiner: Gary W. Counts Filed: November 7, 2001 Confirmation No.: 7939

For: CIRCUITS FOR IN VIVO DETECTION OF BIOMOLECULE

CONCENTRATIONS USING FLUORESCENT TAGS

June 30, 2006

Mail Stop AF Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

# REASONS IN SUPPORT OF APPLICANT'S PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

This document is submitted in support of the Pre-Appeal Brief Request for Review filed concurrently with a Notice of Appeal in compliance with 37 C.F.R. § 41.31 and with the rules set out in the OG of July 12, 2005 for the New Appeal Brief Conference Pilot Program, which was extended until further notice on January 10, 2006.

No fee or extension of time is believed due for this request beyond those otherwise provided for with this submission. However, if any fee or extension of time for this request is required, Applicant requests that this be considered a petition therefore. The Commissioner is hereby authorized to charge any additional fee, which may be required, or credit any refund, to our Deposit Account No. 50-0220.

### **REMARKS**

Applicant hereby requests a Pre-Appeal Brief Review (hereinafter "Request") of the claims finally rejected in the Final Office Action mailed March 3, 2006 (hereinafter "Final Action"). The Request is provided herewith in accordance with the rules set out in the OG dated July 12, 2005.

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Claims 8, 15-17, and 29-31, 34, 36, and 37 stand rejected under 35 U.S.C. § 102 over U.S. Patent No. 6,551,838 to Santini, Jr. et al. ("Santini"). *Final Official Action, pages 4 and 6.* Applicant respectfully maintains that Santini does not disclose the recitations of independent Claim 8:

A circuit for detecting biomolecules *in vivo*, the circuit comprising an optical radiation source configured for *in vivo* use that emits first optical radiation;

an optical radiation detector configured for *in vivo* use that detects second optical radiation emitted by excited labeled binding molecules; and a processor circuit, coupled to the optical radiation source and the optical radiation detector,

wherein the processor circuit is <u>configured to release</u>
<u>fluorescently labeled antibodies selected to bind with predetermined</u>
<u>Tumor Specific Antigens (TSAs)</u>,

the processor circuit is further configured to activate the *in vivo* optical radiation source after a predetermined first time interval after release of the fluorescently labeled antibodies, the predetermined first time interval selected to allow a first portion of the fluorescently labeled antibodies to bind with local available TSAs and a second portion of the fluorescently labeled antibodies to become remote from the circuit so that the first optical radiation excites the first portion of the fluorescently labeled antibodies bound with the local available TSAs and does not excite the second portion of the fluorescently labeled antibodies that become remote,

the processor circuit is further configured to sense a voltage generated by the *in vivo* optical radiation detector after a second predetermined time interval, the second predetermined time interval being after emission of the first optical radiation has ceased.

Santini does not disclose, for example, a processor circuit configured to release fluorescently labeled antibodies selected to bind with predetermined tumor specific antigens, and configured to activate the *in vivo* optical radiation source after a predetermined first time interval after release of the fluorescently labeled antibodies, and so on as recited above.

The Final Official Action maintains that the circuit in Santini is <u>capable</u> of performing the above functional claim language and, therefore, discloses the

<sup>&</sup>lt;sup>1</sup>In the interest of brevity, Applicant has limited the following remarks to independent Claim 8. However, such limitation is not to be construed as any admission regarding the patentability of the remaining claims or a waver of the right to argue the patentability of Claim 8 based on other grounds or the patentability of any other claim on any ground.

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claimed subject matter. See, for example, Final Official Action, page 3, second and third full paragraphs. Applicant maintains that the standard for anticipation under Section 102 is not whether a circuit discussed in a reference is capable of performing operations that are claimed. Rather, a finding of anticipation requires that there must be no difference between the claimed invention and the disclosure of the cited reference as viewed by one of ordinary skill in the art. See Scripps Clinic & Research Foundation v. Genentech Inc., 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). Accordingly, the theoretical capabilities of the circuit in Santini cannot be the basis of a rejection under section 102.

The Final Official Action also considers that Santini discloses the above recitations without any disclosure of the details recited therein. For example, the Final Official Action states in-part with respect to the pending claims:

These recitations are intended use of the circuit and a recitation of intended use of the claimed invention must result in a structural difference between the claimed and the prior art in order to patentably distinguish the claimed invention form [sic] the prior art. Final Official Action, pages 3-4.

Respectfully, by the logic applied by the Official Action, an unprogrammed processor circuit would anticipate any claimed processor circuit that is programmed to perform a specific task because there is no structural difference between the unprogrammed processor circuit and the programmed processor circuit. Processor circuits are naturally defined by their function, not by an apparatus type structure. As discussed above, the standard for anticipation under Section 102 is not whether a circuit discussed in a reference is **capable** of performing operations that are claimed.

Applicant is aware of the sections of the M.P.E.P. regarding the examination of apparatus claims where a structure is defined by what it is and not what it does. *See for example*, M.P.E.P. section 2114: Apparatus and Article Claims - Functional Language. However, Applicant does not believe that M.P.E.P. section 2114 can be properly applied as the recitations in-issue are functional in nature not apparatus like. Applicant notes that the USPTO guidelines for examination of computer related

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inventions (MPEP 2106) also provides guidance that the processor circuit should be examined based on its function, and not strictly on structure as there may be no structural difference between a claimed processor circuit and a prior art processor circuit even though the two processor circuits are programmed to perform completely different operations.

In view of the above stringent standard under Section 102, Applicant respectfully submits that Santini does not disclose the detailed recitations of Independent Claim 8.

Applicant respectfully submits that independent Claim 8 is patentable over Santini for at least the reasons described above. Therefore, Applicant requests that the Final Official Action be reviewed and reversed by the appeal conference prior to filing of an Appeal Brief.

Respectfully submitted,

Registration No. 44,635

#### CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313/1450, on June 30, 2006.

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